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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,093	11/09/2001	Jeanette McCarthy	MRI-026	4997

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LAHIVE & COCKFIELD, LLP.  
 28 STATE STREET  
 BOSTON, MA 02109

EXAMINER
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COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/008,093

Applicant(s)

MCCARTHY, JEANETTE

Examiner

Gary W. Counts

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-51 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-16 and 46-48, drawn to a method and kit for diagnosing of a cardiovascular disease in a patient, classified in class 435, subclass 6.
  - II. Claims 17-26, drawn to a method for monitoring the progression of cardiovascular disease in a patient, classified in class 436, subclass 811.
  - III. Claims 27-36 and 49-51, drawn to a method and kit for assessing the efficacy of a compound for inhibiting cardiovascular disease in a patient, classified in class 435, subclass 7.1.
  - IV. Claims 37-45, drawn to a method of assessing the efficacy of a therapy for inhibiting cardiovascular disease in a patient, classified in class 436, subclass 501.
2. Inventions I and II are independent and distinct inventions. Invention I is a method of diagnosing or aiding in the diagnosis of a cardiovascular disease in a patient whereas, Invention II is a method for monitoring the progression of cardiovascular disease in a patient. Invention I requires a normal level of thrombospondin marker in a control sample and Invention II does not require this limitation. Invention II requires detecting a subsequent level of thrombospondin marker from a patient and comparing this subsequent level with a previous level and Invention I does not require these limitations.

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3. Inventions I and III are independent and distinct inventions. Invention I is a method of diagnosing or aiding in the diagnosis of a cardiovascular disease in a patient whereas, Invention III is a method of assessing the efficacy of a compound for inhibiting cardiovascular disease. Invention III requires a first sample level of the marker maintained in the presence of a compound and a second sample obtained from the patient and maintained in the absence of the compound and Invention I does not require these limitations.

4. Inventions I and IV are independent and distinct inventions. Invention I is a method of diagnosing or aiding in the diagnosis of a cardiovascular disease in a patient whereas, Invention IV is a method of assessing the efficacy of a therapy for inhibiting cardiovascular disease in a patient. Invention IV requires therapy of a patient and invention I does not require this limitation. Invention I requires normal level of thrombospondin marker in a control sample and Invention IV does not require this limitation.

5. Inventions II and III are independent and distinct inventions. Invention II is a method for monitoring the progression of cardiovascular disease in a patient whereas, Invention III is a method of assessing the efficacy of a compound for inhibiting cardiovascular disease. Invention III requires a first sample level of the marker maintained in the presence of a compound and a second sample obtained from the patient and maintained in the absence of the compound and Invention II does not require this limitation.

6. Inventions II and IV are independent and distinct inventions. Invention II is a method for monitoring the progression of cardiovascular disease in a patient whereas, Invention IV is a method of assessing the efficacy of a therapy for inhibiting cardiovascular disease in a patient. Invention IV requires therapy of a patient and invention II does not require this limitation.

7. Inventions III and IV are independent and distinct inventions. Invention III is a method of assessing the efficacy of a compound for inhibiting cardiovascular disease whereas Invention IV is a method of assessing the efficacy of a therapy for inhibiting cardiovascular disease in a patient. Invention III requires a first sample level of the marker maintained in the presence of a compound and a second sample obtained from the patient and maintained in the absence of the compound and Invention II does not require this limitation. Invention IV requires therapy of an anticoagulant and Invention III does not require this limitation.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for one group is not required for other restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

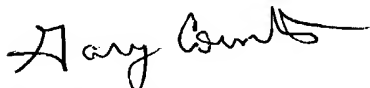
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**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary W. Counts  
Examiner  
Art Unit 1641  
March 25, 2004



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

04/16/04